In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 18-0449V

UNPUBLISHED

KAREN OWENS.

Petitioner.

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: October 31, 2019

Special Processing Unit (SPU); Findings of Fact; Statutory Six Month Requirement; Tetanus Diphtheria acellular Pertussis (Tdap) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

William E. Cochran, Jr., Black McLaren Jones Ryland & Griffee, P.C., Memphis, TN, for Petitioner.

Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On March 27, 2018, Karen Owens filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.,² (the "Vaccine Act"). Petitioner alleges that she suffered the Table injury of shoulder injury related to vaccine administration ("SIRVA") after receiving a tetanus, diphtheria, acellular pertussis ("Tdap") vaccination on April 13, 2015. Petition at 1, ¶ 2. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. <u>44 U.S.C. § 3501</u> note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, <u>100 Stat. 3755</u>. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of <u>42 U.S.C. § 300aa (2012)</u>.

For the reasons discussed below, I find Petitioner suffered the residual effects of her injury for more than six months.

I. Relevant Procedural History

Shortly after filing her petition, Ms. Owens filed her medical records and affidavit. Exhibits 1-9, filed Mar. 29, 2018, ECF No. 6. On May 2, 2018, Petitioner filed a letter and curriculum vitae from Allain A. Girouard, M.D. Exhibits 10-11, ECF No. 9. Dr. Girouard writes that "[b]ased on [his] treatment and care provided to Ms. Owens since her July 28, 2015, and her MRI on August 13, 2015, [his] diagnosis is that Ms. Owens was suffering from left shoulder tendinosis and bursitis from inflammation from a reaction to the injection." *Id.* at 1. He opines that "[i]t would be reasonable to expect that [Ms. Owens's] left shoulder symptoms associated with that diagnosis would probably persist until at least late October/November, 2015, and possibly longer." *Id.* at 1-2.

On February 20, 2019, Respondent filed a status report indicating he wished to defend this case. ECF No. 19. On May 10, 2019, he filed his Rule 4(c) report, indicating he "has concluded that the evidence does not support a finding that petitioner suffered the residual effects of her alleged injury for more than six months after the administration of the vaccine of that treatment of petitioner's alleged vaccine-related injury resulted in inpatient hospitalization and surgical intervention." *Id.* at 1-2. Respondent adds that except for a failure to meet the statutory six month requirement, he believes "petitioner's alleged injury is consistent with SIRVA that was caused by the administration of petitioner's Tdap vaccination." *Id.* at 6. Respondent argues that Dr. Girouard's letter provides little support for petitioner's assertion that her symptoms persisted for more than six months after her Tdap vaccine because he has not examined her since July 28, 2015, and thus appears to have relied heavily upon petitioner's affidavit, which describes a severity of symptoms in the fall of 2015 that is not consistent with the record." *Id.* at 7.

After reviewing the Rule 4(c) report and record in this case, then Chief Special Master Dorsey³ determined a finding of fact regarding the statutory six month issue was appropriate in this case. <u>ECF No. 26</u>. She set a deadline for the parties' simultaneous briefs. *Id.*

The parties filed their briefs on July 9, 2019. ECF Nos. 28-29. Petitioner filed a response to Respondent's brief on July 30, 2019. <u>ECF No. 31</u>. Petitioner also filed medical literature⁴ and affidavits from her husband, daughter, and second affidavit from herself on May 20 and July 30, 2019. Exhibits 12-15, ECF Nos. 23, 30.

The matter is now ripe for adjudication.

³ Prior to October 1, 2019, this case was assigned to then Chief Special Master Dorsey. She stepped down as Chief Special Master on October 1, 2019, and the case was reassigned to me as the new Chief Special Master.

⁴ As Exhibit 15, Petitioner filed an article which she cited to in her brief. S. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010).

II. Issue

At issue is whether Petitioner continued to suffer the residual effects of her SIRVA for more than six months. § 11(c)(1)(D)(i) (statutory six month requirement).

III. Authority

Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 11(c)(1). A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Vaccine Act § 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Vaccine Act § 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Curcuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

IV. Findings of Fact

I make the findings in this ruling after a complete review of the record to include all medical records, medical literature, affidavits, Dr. Girouard's expert report, and additional evidence filed. Specifically, I base the findings on the following evidence:

• The medical records from the physical therapy ("PT") Petitioner underwent from June 9, 2015 through July 13, 2015 (two to three months after vaccination) show she suffered persistent and severe pain which improved over the course of her treatment. Exhibit 4 at 2-6. At her first PT session, Petitioner described her pain as "persistent and impacting her indep[edent] daily mobility. *Id.* at 2. Noting that her pain interfered significantly with her sleep, Petitioner rated the level of her pain as eight out of ten. At the next session, Petitioner again described her pain as severe and reported that it impacted all use of her left upper extremity. *Id.* At the next three sessions, Petitioner described her pain as severe and deep. *Id.* at 3-4. From June 25, 2015 through her last PT session on July 13, 2015, petitioner reported

- improvement in the intensity of her pain. *Id.* at 4-6. However, Petitioner noted that her pain persisted. *Id.* at 5-6.
- The medical record from Petitioner's July 28, 2015 visit to orthopedist Dr. Girouard indicates Petitioner "had developed more pain with movement with some radiation that goes down into her forearm." Exhibit 5 at 1. That record includes a page regarding the definition of emergency medical condition under Florida law. It appears Dr. Girouard believed Petitioner exhibited "acute clinical findings . . . consistent with the . . . Florida statute." Id. at 3. He prescribed a left shoulder MRI. Id. at 4.
- The results of Petitioner's MRI, performed on August 13, 2015, approximately four months after vaccination, showed mild tendinosis and subacromial/subdeltoid bursitis. Exhibit 5 at 14. "Slightly prominent fluid in the subacromial/subdeltoid bursa" was observed. *Id.*
- In a letter dated April 12, 2018, Dr. Girouard opined that Petitioner's tendinosis and bursitis was due to inflammation from receiving the Tdap vaccine on April 13, 2015 and that her left shoulder symptoms would have persisted until at least October/November 2015, possibly longer. Exhibit 10 at 1-2. Describing the results of the physical examination he performed on July 28, 2015, Dr. Girouard noted Petitioner "demonstrated a painful arc of motion in her shoulder from 90-110 degrees with a painful deltoid inflammation at the old injection site." *Id.* at 1. He also noted Petitioner "had some pain in her acromioclavicular joint, her deltoid muscle, and the posterior of the scapula area with mild tenderness to palpitation." *Id.* He described the results of Petitioner's August 13, 2015 MRI and explained that "[his] office contacted Ms. Owens after the August 13, 2015 MRI to inform her of the results and that no surgery would be needed." *Id.*
- In her first affidavit, Petitioner recalled that a nurse in Dr. Girouard's office contacted her regarding the results of her August 13, 2015 MRI. Exhibit 1 at 8. She maintains that she never scheduled a follow-up appointment, however, due to her busy work and family life schedule, and the fact that she was able to adequately manage her pain with over the counter medications, her home exercise program ("HEP"), and rest. *Id.* at 9. Petitioner repeated these claims in her second affidavit. Exhibit 14 at 2-3. She provided additional details regarding her busy work and family life and added that she believed her SIRVA would resolve over time. *Id.* at 5-8.
- Petitioner's husband and daughter provided affidavits detailing instances through Thanksgiving and Christmas 2015 when they noticed Petitioner's left shoulder pain interfering with her ability to perform specific tasks. Exhibits 12-13.

The medical records establish Petitioner suffered persist and constant left shoulder pain through at least the end of July 2015, three months post-vaccination. The medical

record from Petitioner's July 28, 2015 visit to Dr. Girouard establishes that Petitioner's pain was intensifying at that time. Exhibit 5 at 1.

Nevertheless, Petitioner maintains she was able to manage her continued pain without professional medial intervention through over-the-counter medications, a HEP, and rest, and thus did not seek further medical treatment after her August 13, 2015 MRI (four months post-vaccination). Exhibit 1 at ¶ 9; Exhibit 14 at ¶ 3. Dr. Girouard's letter supports Petitioner's assertions as he confirms that she was provided the results of her MRI telephonically by a nurse in his office and informed that she did not require surgery. Exhibit 10 at 1. Had he indicated further treatment, such as surgery, was needed, Petitioner would have had more motivation to schedule a follow-up appointment.

Petitioner's claims of a busy work and family life are supported by her husband and daughter. Additionally, they provided detailed examples of times when they observed Petitioner's ongoing shoulder pain. Exhibits 12-13. These examples, provided in sworn statements, provide support for Petitioner's claims.

Most importantly, Petitioner's treating orthopedist, Dr. Girouard, has opined that Petitioner would have likely continued to experience symptoms of her SIRVA through at least November 2015, possibly longer. Exhibit 10. Although Dr. Girouard attached Petitioner's affidavit to his report (*id.* at 2), he clearly states that he is basing his opinion on his treatment and care of Ms. Owens and the results of her August 13, 2015 MRI (*id.* at 1). To support his opinion, he describes in great detail Petitioner's condition when he treated her on July 28, 2015. *Id.*

Given all of the above and despite a lack of medical records from September to the end of the fall of 2015, I find there is preponderant evidence to establish Petitioner suffered the residual effects of her injury for more than six months. Specifically, I find Petitioner suffered the effects of her injury at least through November 2015.

V. Scheduling Order

Given my findings of fact regarding the sequelae of Petitioner's injury, Respondent should evaluate and provide his current position regarding the merits of Petitioner's case.

Respondent shall file a Status Report regarding his current position by no than Monday, December 02, 2019.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master